

Remarks

Claims 6-12 are pending. A copy of all of the pending claims as they are believed to have been amended is attached to this Amendment as an appendix.

The claims have been amended to be directed to heart valves and blood vessels formed by seeding cell-matrix constructs with specific types of cells. Support is found at page 11, lines 5-11, and the examples at page 13, line 21 to page 16, line 9. The claims have also been limited to a synthetic biodegradable polymeric matrix. Support is found at page 6, line 25-page 7, line 7.

Rejection Under 35 U.S.C. § 103

Claims 6-12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,514,791 to Sparks ("Sparks"), in combination with U.S. Patent No. 4,801,299 to Brendel, et al. ("Brendel"), U.S. Patent No. 4,902,289 to Yannas ("Yannas"), and U.S. Patent No. 5,772,695 to Orton ("Orton"). Applicants respectfully traverse this rejection.

The Claimed Invention

The claims have been amended to define a method for making heart valves or blood vessels, by seeding a mixture of cells into a fibrous matrix, then implanting it.

Sparks

Sparks is directed to growing tissue on a solid stainless steel tube. (see col. 3, lines 29-34) There is no mention of a fibrous matrix; There is no mention of forming a matrix out of a polymer.

The tube may be prefilled with a patient's own blood. Sparks teaches that "the blood will immediately clot within the [tube] so that it will not escape through perforations." (col. 3, lines

74-75) Once in the patient's body, the blood is absorbed and replaced with the invading connective tissue. This is not the same as seeding the matrix with cells. There is nothing that would lead one to make a heart valve or blood vessel.

Brendel

Brendel is directed to cell-free extracellular matrices for implantation into the body. Brendel teaches that the "extracellular membranes, nucleic acids, lipids, and cytoplasmic components" must be removed before the matrix is implanted in a patient. (see col. 2, lines 28-31). Brendel takes natural body tissue from animals and humans and then washes the tissue with detergents to remove cellular components from the tissue to obtain sterilized tissue which can then be implanted into a human. (see col. 4, lines 15-30) All of the tissue is obtained upon autopsy or sacrifice. The decellularized tissues are implanted into the body without being seeded with cells. Brendel does not teach or suggest seeding and implanting a matrix into a site.

Yannas

Yannas is directed to a multilayer blood vessel prosthesis. The prosthesis is thromboresistent. Yannas does not disclose a synthetic polymeric fibrous matrix. Yannas discloses a collagen-aminopolysaccharide material (col. 7, lines 21-29). This material is biodegradable but does not have the necessary mechanical and structural properties that applicants' materials have, as demonstrated by the examples.

Orton

Orton is directed to modified grafts. Orton teaches treating xenogeneic or allogeneic tissue with a growth factor and native cells before implantation in a patient. Orton does not teach or suggest making heart valves or blood vessels by seeding a synthetic fibrous matrix with a mixture of cells.

The Combined References

Nothing in these references teaches or suggests combining them. Sparks teaches that a stainless steel tube is useful as an implant material. Yannas teaches using a collagen-glucosaminoglycan material to make an implant. There is nothing to teach making a fibrous synthetic matrix which is seeded with a mixture of a distinct type of cells to form heart valves or blood vessels.

Allowance of claims 6-12, as amended, is respectfully solicited.

Respectfully submitted,



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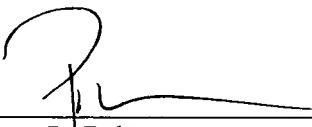
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I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.



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